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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/622,915 11/17/00 NAKAMURA

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022850 HM12/0315
OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON VA 22202

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| EXAMINER |
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| BUTLER, T | |
| ART UNIT | PAPER NUMBER |

1636
DATE MAILED:

03/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/622,915

Applicant(s)

NAKAMURA ET AL.

Examiner

Thomas Butler

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 2,4,6,8,11,14,18 and 20 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

Claims 2, 4, 6, 8, 18, and 20 are objected to because of the following informalities: claim limitations enclosed by parentheses are not permitted by the office. Appropriate correction is required.

Claims 11 and 14 are objected to because of the following informalities: claims 11 and 14 have brackets, [], in the claims. These should be deleted as they can be confused with the bracketing used in amending claims. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 4, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedman et al., J. Am. Chem. Soc., (1993), Vol. 115, No. 15, pp. 6506-9 and Nakamura et al., Bull. Chem. Soc. Jpn., (1996), Vol. 69, No. 8, pp. 2143-2151.

Claims 1, 2, 3, 4, and 17 are drawn to a fullerene derivative having 1 to 4 nitrogen containing hydrophilic side chain (s) or a salt thereof. Furthermore, claims 2, 3, and 4 stipulate

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that the nitrogen containing hydrophilic side chain is "a hydrocarbon group which has 1 or 2 straight-chain or branched-chain substituent group (s) each comprising 1 to 10 nitrogen atom (s) and 2 to 30 carbon atoms, and is configured to be bonded to 1 to 2 of the 2 to 8 sp^3 carbon atoms present on the fullerene core."

Friedman (p. 6508, Figure 2) and Nakamura (p. 2144) teach fullerene derivatives having 1 to 4 nitrogen containing hydrophilic side chains. Examples are given where the nitrogen containing hydrophilic side chains are hydrocarbon groups that have 1 or 2 straight-chain or branched-chain substituent group (s) comprising 1 to 10 nitrogen atom (s) and 2 to 30 carbon atoms and configured to be bonded to 1 to 2 of the 2 to 8 sp^3 carbon atoms of the fullerene. Friedman and Nakamura thus, anticipates the instantly claimed invention (claims 1, 2, 3, 4, and 17).

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, 3, 4, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Friedman et al. (WO 9519949) ^{or} and Murphy et al (U.S. Patent No. 6162926).

Claims 1, 2, 3, 4, and 17 are drawn to a fullerene derivative having 1 to 4 nitrogen containing hydrophilic side chain (s) or a salt thereof. Furthermore, claims 2, 3, and 4 stipulate that the nitrogen containing hydrophilic side chain is "a hydrocarbon group which has 1 or 2 straight-chain or branched-chain substituent group (s) each comprising 1 to 10 nitrogen atom (s) and 2 to 30 carbon atoms, and is configured to be bonded to 1 to 2 of the 2 to 8 sp^3 carbon atoms present on the fullerene core."

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Friedman (pp. 10, 12, 41, and 44-45) and Murphy (col. 6, lines 22-60; col. 7, lines 15-44; col. 12, line 30; col. 13, lines 35-60; col. 14, lines 1-15) teach fullerene derivatives having 1 to 4 nitrogen containing hydrophilic side chains. Examples are given where the nitrogen containing hydrophilic side chains are hydrocarbon groups that have 1 or 2 straight-chain or branched-chain substituent group (s) comprising 1 to 10 nitrogen atom (s) and 2 to 30 carbon atoms and configured to be bonded to 1 to 2 of the 2 to 8 sp^3 carbon atoms of the fullerene. Friedman and Murphy thus, anticipates the instantly claimed invention (claims 1, 2, 3, 4, and 17).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16, 18-21, and dependents are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10, and 21 provide for the use of a fullerene derivative, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10

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USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2, 4, 6, 8, 18, and 20 recite the broad recitation "(provided, however, that there may exist a cross-linking moiety comprising an alkylene group bridging two nitrogen-containing hydrophilic side chains)", and the claim also recites "a hydrocarbon group which has 1 or 2 straight-chain or branched-chain substituent group (s) ...bonded to...carbon atoms present on the fullerene core", which is the narrower statement of the range/limitation.

Claims 2, 4, 6, 8, 18, and 20 recite "(provided however, that there may exist a cross-linking moiety...)", which is unclear as to how this limitation relates to the rest of the claim limitations.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims a "DNA compaction" but the term is not defined in the claims nor is it defined in the specification. Therefore, the examiner can not determine what exactly is a "DNA compaction."

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Regarding claims 9 and 10, the word "as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 11 and 14 end with the phrase "...exclusive of the fullerene derivative...", does this mean that the specific chemical structure is excluded or included?

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10, and 21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

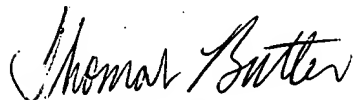
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Butler whose telephone number is (703) 308-8361. The examiner can normally be reached on Monday thru Friday from 8:30am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.



Thomas Butler
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DAVID GUZO
PRIMARY EXAMINER

